Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK



7848

Accredited to ISO/IEC 17025:2017

Medical Engineering Technologies Ltd

Issue No: 019 Issue date: 29 July 2024

Units 13 & 16 Contact: Mrs Naomi Allkins
Holmestone Road Tel: +44 (0) 1304 213223

Dover E-Mail: naomi.allkins@met.uk.com

CT17 0UF Website: www.met.uk.com United Kingdom

Testing performed at the above address only

DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---------------------------|---|--|
| MEDICAL PACKAGING | Requirements for materials, sterile barrier systems and packaging systems for the following tests | BS EN ISO 11607: Part1:2019 for the associated tests as listed on this schedule only |
| | Accelerated ageing | ASTM F1980-21 |
| | Visual Inspection for flaws and channels in seals | ASTM F1886 ASTM F1886M -2016 |
| | Seal Strength test by rupture pressure | ASTM F1140/F1140M-13- ASTM F2054-13 |
| | Seal Integrity test by dye penetration | ASTM F1929-23 |
| | Seal strength by peel force | BS EN 868-5:2018 ASTM F88/F88M-23 |
| | Trace gas integrity testing using hydrogen | IHM WI 24 Jun 2020 IHM WI 66 June 2022 |
| | Needle based injection systems for medical use | BS EN ISO 11608-1:2022 |
| | Air transport simulation | IHM WI 54 March 2021 |
| | Break loose & Glide force | IHM WI 52 May 2022 based on ISO 11040-8:2016 Clause:6.2 |
| | Needle cap removal force | IHM WI 52 May 2022 based on ISO 11040-4:2016 G6 |
| | Leak test | IHM WI 57 April 2021 based on ISO 11040-4:2016 G2 |
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Assessment Manager: PL Page 1 of 3



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| MEDICAL PACKAGING (cont'd) | Shipping Containers and systems sequential performance tests | ASTM D4169-23 Excluding: - 14 Schedule G -Simulated Rail Switching 15 Schedule H – Environmental Hazard 16 Schedule I – Low Pressure (High Altitude) Hazard |
| | Testing of Packages for Single Parcel Delivery Systems | ASTM D7386 – 16 Excluding: - 12 Schedule I Bridge Impact 13 Schedule J Hazard drop 14 Schedule K – High Altitude 16 Tip Over Test (D6179) 17 Rotational Edge Drop Test (D6179) |
| | Conditioning Containers, Packages, or Packaging Components for Testing | ASTM D4332-22 |
| | Max Temperature +60 °C Min Temperature -30 °C Relative Humidity 15 to 90 % | |
| | Drop test of loaded containers by free fall | ASTM D5276-19 |
| | Concentrated Impacts to Transport Packages | ASTM D6344 - 04(2017) |
| | Random Vibration Testing of Shipping Containers | ASTM D4728-17 ASTM D999-08(2015) – Method A1 only |
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Assessment Manager: PL Page 2 of 3



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| MEDICAL PACKAGING (cont'd) | Environmental testing - Vibration (sinusoidal) Vibration Test Parameters Max Payload 300 kg Max acceleration 100 g Frequency Range 2-2000 Hz Displacement 51 mm (p-p) Max velocity 1.8 m/s Peak Force 600 kgf Vertical only at ambient | BS EN 60068-2-6:2008 | |
| | Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads Up to 2549 kgf | ASTM D642-20 | |
| END | | | |

Assessment Manager: PL Page 3 of 3